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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,506	01/28/2004	Michael J. Welsh	P04385US02	3490

22885 7590 09/22/2004

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,506	WELSH ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 28 January 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claims 1-10 are presented for prosecution on the merits.

Claim Rejection(s)—35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 7, 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for xylitol, does not reasonably provide enablement for any non-ionic osmolyte with low transepithelial permeability. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

1. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among the factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claimed; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention

The claims are drawn to methods of killing infectious cells comprising administering an amount of an non-ionic osmolyte with low transepithelial permeability.

(2) The state of the prior art

The compounds of the invention can be any compound which is a non-ionic osmolyte having low transepithelial permeability. The art discloses known numerous compounds that have such an activity, all of them differing structurally and chemically.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and chemical art is high.

(5) The breadth of the claims

The claims are very broad and encompass any compound that may be a non-ionic osmolyte with low transepithelial permeability.

(6) The amount of direction or guidance presented

Applicant's specification provides guidance for and is only enabled for the use of xylitol in the claimed methods. However, the specification provides no guidance to enable one of ordinary skill in the art to use the invention commensurate in scope with the claims, which, as stated above, are broad and encompass numerous compounds that may be non-ionic osmolytes with low transepithelial permeability. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled in cases involving chemicals and chemical compounds, which differ radically in their properties, it must appear in an applicant's specification either by the enumeration of a

sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combination included in the claims are capable of accomplishing the desired result." Applicant's specification does not set forth a representative number of examples of non-ionic osmolytes with low transepithelial permeability, which would be capable of performing the claimed methods.

(7) The presence or absence of working examples

The examples in Applicant's specification describe using xylitol for application to epithelia. Thus, the specification enables one of ordinary skill in the art to use xylitol in the claimed methods.

(8) The quantity of experimentation necessary

Since (1) the claims are very broad and encompass the use of numerous compounds, (2) the specification does not provide a representative number of compounds capable of performing the claimed methods such that the scope of enablement is reasonably correlated to the scope of protection sought by the claims, and (3) compound structure and activity for pharmaceutical use must be determined from cases to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all non-ionic osmolytes with low transepithelial permeability which would be capable of performing the claimed methods.

Claims Rejection(s)—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Uhari et al., 5,719,196 (already of record).

Uhari et al. disclose methods of treating or preventing infections such as otitis media, upper respiratory infections, acute bronchitis, sinusitis and conjunctivitis, the methods comprising orally administering (tablets, powders or lozenges) effective amounts of xylitol. Uhari et al. teach that the xylitol exhibits a growth inhibiting effect against pneumococci. Please see col. 1, lines 55-61; col. 2, lines 1-30; claims 1-10.

The claims are anticipated by Uhari et al. because Uhari et al. disclose administration of an identical agent, i.e. xylitol, to a host using Applicant's claimed method steps. Accordingly, a reduction in the ionic strength of surface fluid leading to antimicrobial activity against infectious cells is an inherent characteristic of the method.

Claims 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Franz et al., 5,527,831.

Franz et al. disclose a method of treating intraocular pressure by topically administering to the eye of an individual in need of treatment an effective amount of a composition comprising xylitol. Please se col. 4, lines 10-20.

The claims are anticipated by Franz et al. because Franz et al. disclose administration of an identical agent, i.e. xylitol, to a host using Applicant's claimed method steps. Accordingly, a reduction in the ionic strength of surface fluid leading to antimicrobial activity against infectious cells is an inherent characteristic of the method.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 7-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones 6,054,143 (already of record).

Jones discloses a method of treating or preventing upper respiratory infections, such as otitis media and sinusitis by nasally administering effective amounts of xylitol. Jones also discloses a method of reducing infections of the nasopharynx by cleaning the nasopharynx and reducing the population ofpathogenic bacteria that reside there, the method comprising nasally administering effective amounts of xylitol. Jones discloses that nasal administration of xylitol results in cleaning of the nasopharynx, reduction of the bacterial count in the nasopharynx and a reduction of infections associated with those baceria. Please see col. 2, lines 22-60; col. 3, lines 5-50.

The claims are anticipated by Jones because Jones teaches administration of an identical agent, i.e. xylitol, to a host using Applicant's claimed method steps. Accordingly, a reduction in the ionic strength of surface fluid leading to antimicrobial activity against infectious cells is an inherent characteristic of the method.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 9-10 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/27922 ('922).

WO '922 teaches a method for treating vaginal yeast infections, wherein the method comprises topically administering to the vagina an effective amount of a composition containing xylitol. Please see page 7, lines 5-8.

The claims are anticipated by WO '922 because WO '922 discloses administration of an identical agent, i.e. xylitol, to a host using Applicant's claimed method steps. Accordingly, a reduction in the ionic strength of surface fluid leading to antimicrobial activity against infectious cells is an inherent characteristic of the method.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-4, 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No.

6,716,819. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428. 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are generic to all that is recited in claims 1-16 of USPN '819. That is, the claims of USPN '819 fall entirely within the scope of the claims of the instant application. In other words, claims 1 -16 are anticipated by claims 1-16 of USPN '819. Specifically, the claims of USPN '819 recite substantially identical methods as those claimed in the instant application, wherein the active transepithelial salt transport on the liquid layer covering the airway surface is reduced and endogenous antimicrobial killing of infectious microbial cells is promoted.

Conclusion

Claims 1-10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Sept. 20, 2004

Cybille Delacroix-Muirheid
Patent Examiner Group 1600